510(k) Summary

ADMINISTRATIVE INFORMATION

Manufacturer Name:	X-spine Systems, Inc. 452 Alexandersville Rd. Miamisburg, OH 45342 Telephone (937) 847-8400 FAX (937) 847-8410
Official Contact:	David Kirschman, M.D. Chief Medical Officer
Date Prepared:	June 26, 2013

AUG 14 2013

DEVICE NAME

Trade/Proprietary Name:	Irix-C™ Cervical Integrated Fusion System
Common Name:	Intervertebral body fusion device
Device Class:	Class II
Regulation Number:	§888.3080
Product Code:	OVE
Classification Name:	Intervertebral Fusion Device with Integrated Fixation, Cervical

ESTABLISHMENT REGISTRATION NUMBER

The X-spine Systems, Inc. establishment registration number is 3005031160. The owner/operator number for X-spine Systems, Inc. is 9063903.

INDICATIONS FOR USE

The Irix-C Cervical Integrated Fusion System is a stand-alone cervical intervertebral fusion device intended for spinal fusion procedures at one level (C3 – T1 inclusive) in skeletally mature patients for treatment of degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). Implants are to be implanted via an open, anterior approach and packed with autogenous bone graft. Patients should receive at least six (6) weeks of non-operative treatment prior to treatment with a cervical intervertebral fusion device.

DEVICE DESCRIPTION

The Irix-C Cervical Integrated Fusion System is a stand-alone intervertebral fusion device to restore biomechanical height and act as an aid in fusion of the cervical spine in anterior discectomy procedures. The device is generally boxed shaped with teeth on the superior and inferior faces of the device. The Irix-C implant is manufactured from both titanium alloy (Ti6Al4V) in accordance with ASTM F136 and Invibio PEEK Optima LT1 in accordance with ASTM F2026, or from Ti6Al4V titanium alloy alone. The device will be supplied with the option of having the superior and inferior surfaces of the device plasma coated with medical-grade commercially pure titanium (CP Ti) per ASTM F1580. The device is then secured in location through the use of bone screws, also manufactured from titanium alloy (Ti6Al4V) per ASTM F136. The devices are provided in various sizes and screws are offered in multiple lengths to adjust for variations in patient anatomy.

The implant components are provided clean and non-sterile. These devices are sterilized by a healthcare professional using a steam autoclave in accordance with the instructions for use provided by X-spine Systems Inc., as well as the instructions provided by the manufacturer of the autoclave.

EQUIVALENCE TO MARKETED PRODUCT

X-spine Systems, Inc. has submitted information to demonstrate that, for the purposes of FDA's regulation of medical devices, the Irix-C Cervical Integrated Fusion System is substantially equivalent to predicate devices based on a comparison including the following characteristics:

- FDA Product Code
- Indications for Use
- Surgical Approach
- Anatomical Region
- Implant Materials
- Product Dimensions
- Mechanical Performance

PREDICATE DEVICES

- Globus Medical, Inc. – COALITION Spacer (K083389)
- Centinel Spine, Inc. – STALIF-C (K120819)
- X-spine Systems, Inc. – Calix PC Spinal Implant System (K112036)

PERFORMANCE DATA

The implant components were tested using the following standards:

ASTM F2077 – *Test Methods for Intervertebral Body Fusion Devices*

- Static and Dynamic Compression
- Static and Dynamic Torsion

ASTM F2267 – *Standard Test Method for Measuring Load Induced Subsidence of an Intervertebral Body Fusion Device under Static Axial Compression*

In addition to the above standard testing, expulsion, screw back out and dissociation tests were performed as part of this submission. There are no cited standard for these tests.

The mechanical testing results indicate that the Irix-C Cervical Integrated Fusion System is substantially equivalent to predicate device performance and is capable of safely and effectively performing in accordance with its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 14, 2013

X-Spine Systems, Incorporated
David Kirschman, M.D.
Chief Medical Officer
452 Alexandersville Road
Miamisburg, Ohio 45342

Re: K131951
Trade/Device Name: Irix-C™ Cervical Integrated Fusion System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral body fusion device
Regulatory Class: Class II
Product Code: OVE
Dated: June 26, 2013
Received: June 27, 2013

Dear Dr. Kirschman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin L. Keith

For

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K131951

Device Name: Irix-C™ Cervical Integrated Fusion System

Indications for Use:

The Irix-C Cervical Integrated Fusion System is a stand-alone cervical intervertebral fusion device intended for spinal fusion procedures at one level (C3 – T1 inclusive) in skeletally mature patients for treatment of degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies). Implants are to be implanted via an open, anterior approach and packed with autogenous bone graft. Patients should receive at least six (6) weeks of non-operative treatment prior to treatment with a cervical intervertebral fusion device.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Anton E. Dmitriev, PhD
Division of Orthopedic Devices